PETITION FOR EXTENSION OF TIME

Applicants hereby petition for a one (1)-month extension of time to extend the period for response from October 10, 2002 up to and including November 10, 2002. However, since November 10, 2002 fell on a Sunday and November 11, 2002 was a Federal holiday, action may be taken on the next succeeding business day. (37 C.F.R. §1.17(a)). Therefore, Applicants response is timely and falls within the one-month period of extension. The Commissioner is hereby authorized to charge the Fifty-five Dollar ($55.00) fee for a small entity and any additional fees due in connection with this petition or credit any overpayment to Deposit Account No. 23-1703.

REMARKS

I. Election/Restriction

A restriction requirement under 35 U.S.C. §121 was issued in the subject application. The Examiner alleges that the subject application contains the following inventions or groups of inventions which are independent and patentably distinct:

> **Group I**: claims 1-17 and 41-55 directed to a medical device coated with an antibody and a matrix;
>
> **Group II**: claims 18-24 directed to the matrix composition;
>
> **Group III**: claims 25-28 directed to a method of coating the medical device; and
>
> **Group IV**: claims 29-40 directed to a method of treatment.

The Examiner further alleges that the application contains claims directed to the following patentably distinct species and subspecies within each group, and that an election of a subspecies within each of the identified groups must be made.

Group I: Subspccies: 1) Medical device
- a) stent, or
- b) graft

2) Matrix
- c) synthetic material,
- d) naturally occurring material, or
- e) fullerene

3) Antibody attachment
- f) noncovalently, or
- e) covalently

Group II: Subspecies: 1) Matrix
- a) synthetic material,
- b) naturally occurring material or
- c) fullerene

Group III: Subspecies: 1) Antibody attachment
- a) covalently, or
- b) tethered covalently

Group IV: Subspecies: 1) Matrix
- a) synthetic material,
- b) naturally occurring material, or
- c) fullerene

2) Vessel Type
- a) artery, or
- b) vein

3) Medical Device
- a) stent, or
- b) graft

4) Matrix attachment
- a) noncovalently, or
- b) covalently

Applicants provisionally elect, with traverse, the invention of Group I, claims 1-17 and 41-55 directed to a medical device coated with an antibody and a matrix; wherein the medical device is a stent, the matrix is a fullerene and the antibody attachment is covalent, i.e., Group I, 1a, 2e, 3e (Applicants believe the Examiner meant 3g).

II. Traversal of the Restriction Requirement

Applicants respectfully traverse and request withdrawal of the restriction requirement as to the inventions of Groups I-IV for the following reasons.

A. Groups I and II

The Examiner has treated the inventions of these groups as combination and subcombination. According to MPEP §806.05(c), inventions in this group are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, ***and*** (2) that the subcombination has utility by itself or in other combinations.

Applicants respectfully submit that the Examiner has incorrectly concluded that the combination, as claimed, does not require the particulars of the subcombination, as claimed. Specifically, the Examiner alleges that the medical device of Group I does not require "that the at least one type of antibody be of a therapeutically effective amount".

In contrast to the Examiner's conclusion, the claims expressly provide that the medical device of Group I is coated with a therapeutically effective amount of an antibody. The incorporation of a therapeutically effective amount of antibody in a matrix is necessary to stimulate *in vivo* the adherence of endothelial cells to the surface of the coated device, thereby

preventing restenosis and other thromboembolic complications that result from implantation of the medical device (page 7, lines15-18). If it were possible for the claimed device to not contain an effective amount of antibody, as suggested by the Examiner, the intent, purpose and function of the claimed invention would be destroyed. Although the claims of Group I do not expressly state the function to be achieved by the effective amount of antibody, that function is described by the specification which provides guidelines as to the intended utilities and how the uses could be effected.

The requirements of MPEP §806.05(c) are twofold and, in view of the foregoing, the requirements of the first test are not satisfied. Specifically, the medical device of Group I requires the particulars of the subcombination in order that the intent, purpose and function of the invention of Group I is fulfilled. This is sufficient reason to join the inventions of Groups I and II and examine claims 1-24 and 41-55 in the same application.

It is further submitted that the subcombination does not have a separate utility. The invention of Group II is directed to a composition for coating a medical device. At page 7, lines 6-14, the specification provides the following definition:

> As used herein, "medical device" refers to a device that is introduced temporarily or permanently into a mammal for prophylaxis or therapy of a medical condition. These devices include any that are introduced subcutaneoulsy, percutaneoulsy or surgically to rest within an organ, tissue ***or*** lumen. (Emphasis added).

Therefore, in view of the preceding definition, the subcombination does not have a separate utility. As defined by the specification, a medical device is characterized by the same utility, i.e., resting within an organ, tissue ***or*** lumen for prophylaxis or therapy of a medical condition. The recitation of organ, tissue or lumen in the alternative indicates that the nature and

position of the medial device within the body is immaterial so long as the device satisfies the definitional requirement. Applicants respectfully submit, therefore, that the Examiner's treatment of an artificial heart valve, stent, graft, etc. as having a separate utility is not supported by the specification.

Finally, there is an overlap between the recited features of the respective inventions of Group I and II, i.e., a coating composition comprising a matrix and antibody which reacts with an endothelial cell surface antigen. Accordingly, Applicants submit that there would be no undue burden upon the Examiner to search and examine the claims of Groups I and II in the present application. Even though the claims of Groups I and II are classified in different classes, it is reasonable to expect that a thorough search of Group I would and should include a search of Group II.

In conclusion, either one or both of the requirements of MPEP §806.05(c) are not met. The medical device of Group I requires the particulars of the subcombination in order that the intent, purpose and function of the invention of Group I is fulfilled. The subcombination of Group II does not have a separate utility since all medical devices within the meaning of the claimed invention , e.g., an artificial heart valve, stent, graft, etc., are characterized by the same utility, i.e., to rest within an organ, tissue or lumen for prophylaxis or therapy of a medical condition. Moreover, economy of Patent Office resources and those of the Applicants as well as fundamental fairness warrant the withdrawal of the restriction requirement as to the inventions of Groups I and II.

B. <u>Groups I and III</u>

The Examiner has treated the inventions of these groups as process of making and product. According to MPEP §806.05(f), inventions in this group are distinct if it can be shown

that (1) the process as claimed can be used to make other and materially different products ***or*** (2) the product as claimed can be made by another materially different process.

The Examiner has concluded that the claimed process can be used to make other and materially different products. Specifically, on page 3 of the Office Action, the Examiner states that "[t]he method for coating of Group III can be used to make an artificial valve, rather than the stent or graft of Group I".

The invention of Group I is directed to a medical device whereas the invention of Group III is directed to a method for coating that device. Within the meaning of the claimed invention, all medical device are characterized by the same utility, i.e., to rest within an organ, tissue or lumen to for prophylaxis or therapy of a medical condition (p. 7, lines 6-14). This utility is the same for an artificial heart valve, stent or graft. In view of the definition set forth in the specification, medical devices such as an artificial heart valve, stent or graft cannot be considered to be materially different products.

In conclusion, neither of the requirements of MPEP §806.05(f) is met. As defined by the specification, the products prepared by the method of Group III are characterized by the same utility, i.e., to rest within an organ, tissue or lumen to for prophylaxis or therapy of a medical condition and, therefore, medical devices which share this property cannot be considered materially different within the context of the specification. Finally, the Examiner has not established and Applicants submit that the products of Group I cannot be made by another and materially different process.

For all of the foregoing reasons, withdrawal of the restriction requirement as to the inventions claims of Groups I and III is requested.

C. **Groups I and IV**

The Examiner has treated the inventions of these groups as product and process of use. According to MPEP §806.05(h), inventions in this group are distinct if it can be shown that (1) the process for using the product as claimed can be practiced with a materially different product ***or*** (2) the product as claimed can be used in a materially different process of using that product.

The Examiner has concluded that the claimed process of using the product as claimed can be practiced with another materially different product. Specifically, on page 3 of the Office Action, the Examiner states that "[t]he method of treating mammals does not require the medical device to be a stent or graft".

Again, the restriction of Groups I and IV is based on the premise that a stent, graft or artificial heart valve are materially different products. Applicants repeat that medical devices, as encompassed by the claimed invention, are characterized by the same utility, i.e., to rest within an organ, tissue or lumen to for prophylaxis or therapy of a medical condition (p. 7, lines 6-14). In accordance with the claimed method of treatment, the coated medical device is inserted to rest within the lumen of an artery for treating vascular disease such as restenosis. Therefore, Applicant respectfully submits that the treatment of medical devices such as a stent, graft or artificial heart valve as materially different products is contrary to the intent, function and purpose of the claimed invention.

In conclusion, neither of the requirements of MPEP §806.05(h) is met. As defined by the specification, the process for using the products as claimed is the same for all medical devices. Finally, the Examiner has not established and Applicants submit that the products as claimed cannot be used in a materially different process of using that product.

CONCLUSION

Applicants respectfully request withdrawal of the restriction requirement as to Groups I-IV.

The Commissioner is hereby authorized to charge any fees which may be due in connection with this communication to Deposit Account 23-1703.

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Respectfully submitted,

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